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June 28, 2004

Division of Dockets Management (HFA-560)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: FDA Docket No. 2003N-0539, Over-The-Counter Drug Products; Safety and Efficacy Review; Request for Data

Dear Sir/Madam:

We respectfully submit these comments in response to the Food and Drug Administration's ("FDA") request for data and information in connection with its notice entitled "Over-The-Counter Drug Products; Safety and Efficacy Review," ("request for data") published in the Federal Register on December 31, 2003. (*See* 68 Fed. Reg. 75,585). The request for data invited parties to submit information on the following categories of ingredients: nasal moisturizer drug products, urinary analgesic/antiseptic drug products, urinary acidifiers and alkalinizers, aloe vera and urea, and wrinkle remover products.

These comments specifically address the FDA's request for data regarding nasal moisturizer product claims and ingredients. We must respectfully disagree with FDA's position that nasal moisturizers are drug products. Nasal moisturizers have been marketed and used for many years to moisturize, relieve dryness and cleanse the nasal cavity. The FDA has traditionally regulated moisturizers as cosmetics, and on numerous occasions has reaffirmed its position that moisturizers are properly regulated as cosmetics.

Accordingly, we ask that the FDA remove nasal moisturizers from any OTC product review, and to the extent ingredient information is requested, that it be limited to "drug" uses for those ingredients.

I. Nasal Moisturizers are Properly Regulated as Cosmetics

The Federal Food, Drug, and Cosmetic Act ("the Act" or "FDCA") defines cosmetics as "articles *intended* to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance" (FDCA, sec. 201(i)). Drugs on the other hand, are defined by the Act as "(A) articles *intended* for use in the diagnosis, cure, mitigation, treatment, or prevention of disease ... and (B) articles (other than food) *intended* to affect the structure or any function of the body of

man or other animals" (FDCA, sec. 201(g)(1))(emphasis added). Determining whether a product is classified as a cosmetic or a drug therefore depends on the intended use of that product. Courts have consistently held that a product's intended use is inferred from the product's labeling, promotional material, and advertising.[1] Further, the FDA has repeatedly stated that the OTC drug review does not apply to any product for which only cosmetic claims are made.[2]

The FDA, as well as the federal courts[3] have long held moisturizers, making temporary relief of dryness/moisturizing claims, to be cosmetics. Most recently, in the preamble to the final monograph for sunscreen drug products, the Agency stated that if a product is "intended solely to provide cosmetic effects on the skin (e.g., *to moisturize* the skin ...)" the product may be marketed as a cosmetic.[4] The FDA has also specifically listed moisturizers as a "cosmetic product category" under 21 C.F.R. § 720.4(c)(12)(vi). Furthermore, the FDA, in providing guidance to the industry and consumers as to how the law defines a cosmetic, cites moisturizers as the *first* example of the type of product included under the definition of a "cosmetic."[5]

Nasal moisturizer products do not differ in any significant way from other moisturizer products currently being marketed as cosmetics by any number of companies. Nasal moisturizers are marketed as cosmetics to sooth, moisturize, and cleanse dry skin in the nasal cavities. They have been marketed for a number of years with such claims as cosmetics products, and accordingly the public has become familiar with these products as cosmetic moisturizers.

Thus, nasal moisturizer products are properly regulated as cosmetics. Barring any claims that would clearly alter the intended use of the product (i.e., to cure, mitigate, treat, or prevent disease), an argument that nasal moisturizer products should be regulated differently than any other type of moisturizer product on the market can only be described as arbitrary.

II. The FDA Listed Nasal Moisturizer Claims are Cosmetic Claims

In the request for data, the FDA highlighted examples of claims made by several marketed nasal moisturizer products. Some of these examples include:

> "provides soothing moisture to dry, inflamed nasal membranes due to colds, allergies, low humidity, and other minor nasal irritations;" "restores vital moisture to provide

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[1] *See, e.g.*. Brown & Williamson Tobacco Corp. v. Food and Drug Administration, 153 F.3d 122 (4th Cir. 1988); National Nutritional Foods Association v. Mathews, 557 F.2d (2d Cir. 1977); United States v. An Article ... "Sudden Change," 409 F.2d 734 (2d Cir. 1969).

[2] 37 Fed. Reg. 9473 (May 11, 1972) (FDA in discussing procedural regulations regarding OTC review stated "Any product for which only cosmetic claims are made and which is therefore not a drug will not be reviewed."). *See also* 64 Fed. Reg. 27,666, 27,669 (May 21, 1999) (sunscreen products); 48 Fed. Reg. 6820 (February15, 1983)(Skin protectant products); 47 Fed. Reg. 36,492 (August 20, 1982) (Antiperspirant products).

[3] *See., e.g.,* United States v. An Article ... "Sudden Change," 409 F.2d 734, 742 (2d Cir. 1969) (product sold as a moisturizer understood to be a cosmetic).

[4] 64 Fed. Reg. 27,666, 27,669 (May 21, 1999).

[5] Is It a Cosmetic, a Drug, or Both?(or Is It Soap?), U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Cosmetics and Colors, (July 8, 2002), *at* http://www.cfsan.fda.gov/~dms/cos-218.html.

> prompt relief for dry, crusted, and inflamed nasal membranes due to chronic sinusitis, colds, low humidity, overuse of nasal decongestant drops and sprays, allergies, minor nose bleeds, and other minor nasal irritations;" "a nasal moisturizer formulated to be physiologically compatible with nasal membranes, providing soothing relief for clogged nasal passages without stinging or burning;" "restores moisture to relieve dry, inflamed nasal membranes due to low humidity, colds, allergies, and overuse of nasal decongestants." 68 Fed. Reg. 75,585, 75,587 (December 31, 2003).

The claims listed by the FDA in the request for data do not signal an intent to cure, mitigate, treat or prevent disease. A closer examination reveals that these claims are "moisturizing" claims that simply refer to the possible causes of dry nasal membranes. For example, reviewing the claims listed above, any specific disease listed in the claim is modified with the phrase "*due to.*" Clearly, the statement "provides soothing moisture to dry, inflamed nasal membranes due to colds ..." is not indicating a treatment for the cold, or other specific disease, nor is it claiming to mitigate or cure that disease. This claim merely states that the product will provide moisture to dry skin that *may be associated with* a cold, or other condition. Nor do these statements claim to treat any particular symptom or cause of disease. As discussed above, it is well settled that products offered to moisturize are cosmetic products and the listed claims are clearly for cosmetic moisturizing of nasal membranes.

Furthermore, were one to remove all references to any specific disease(s) or conditions from the claims for nasal moisturizers, and merely label these products as "providing moisture, soothing and cleansing," we believe that any doubt regarding the classification of these products as cosmetics would be removed. Taken in view of this fact, it is clear that nasal moisturizers are properly classified as cosmetics, and the claims highlighted by the FDA are appropriate for cosmetic products.

III. Information Regarding the Ingredients of Nasal Moisturizers

The FDA's request for data specifically invited parties to submit information on "categories of ingredients," including "nasal moisturizer drug products."[6] We reemphasize that nasal moisturizers are properly classified as cosmetics. As discussed above, it is the intended use of a product that determines its classification as a cosmetic or a drug, not its ingredients or even its effect.[7] The FDA confirmed this position in the tentative final monograph for "skin protectant drug products," where it stated that the concentration ranges, limitations, warnings, and directions established for active ingredients in drug products only covered the use of those active ingredients when used in a *drug product*, and the limitations, warnings, etc., in the monograph would not apply to those same ingredients when used in products intended solely for use as

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[6] *See* 68 Fed. Reg. 75,585, 75,587 (December 31, 2003).

[7] *See., e.g.,* National Nutritional Foods Association v. Mathews, 557 F.2d (2nd Cir. 1977)(court overruled FDA regulations that would have classified high doses of vitamins as drugs based solely on the level of the vitamins in a product.); United States v. An Article ... "Sudden Change," 409 F.2d 734, 742 (2d Cir. 1969) (Regardless of the actual physical effect of a product, it will be deemed a drug where the labeling and promotional claims show intended uses that bring it within the drug definition.).

cosmetics.[8] Accordingly, the mere presence of an "active" ingredient in a cosmetic product does not turn that product into a drug.

Nonetheless, we note that the ingredients listed by FDA in the request for data are commonly used in cosmetic products. For example, the principal ingredient in the majority of these nasal moisturizer products is a saline solution, composed of water and sodium chloride. Sodium chloride is listed in the *International Cosmetic Ingredient Dictionary and Handbook* as a cosmetic ingredient for use in moisturizing preparations, cleansing products, and many other cosmetics.[9] (CAS 7647-14-5; EINECS 231-598-3). Further, the FDA recognizes sodium chloride solutions as "inactive" ingredients at concentrations from less than 1% to as high as 90% (CAS 007647145).[10] However, to the extent that the FDA has an interest in the ingredients used in cosmetic nasal moisturizer products, FDA should understand that additional cosmetic ingredients are included in nasal moisturizer products. For example, in addition to normal saline, buffered isotonic saline solution, and saline phosphate buffer solution, currently marketed cosmetic nasal moisturizers contain varying levels of saline, including hypertonic saline solution (3% and greater).

Conclusion

Nasal moisturizer products labeled with claims to moisturize, relieve dryness, and cleanse are properly regulated as cosmetics. The FDA should address any nasal spray products that make drug claims on an individual basis rather than reclassifying a category of products that are cosmetics. Further, any request for information regarding ingredients under the OTC drug review should clearly limit data collection to "drug" uses for those ingredients.

Respectfully submitted,

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[8] 48 Fed. Reg. 6820, 6822 (February15, 1983).

[9] International Cosmetic Ingredient Dictionary and Handbook, The Cosmetic, Toiletry, and Fragrance Association, Inc. (9th ed. 2002).

[10] FDA Inactive Ingredient for Approved Drug Products Database, http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm